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10/729,364	12/05/2003	Raymond W. Sze	UNIV0162	8253

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EXAMINER	
UTAMA, ROBERT J	
ART UNIT	PAPER NUMBER
3715	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/729,364	SZE ET AL.	
	Examiner	Art Unit	
	ROBERT J. UTAMA	3715	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,5,7-27 and 52-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4-5, 7-27, 52-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the application

1. This office action is a response to the amendment and argument filed on 03/30/2009. The current status of the application are as follow: claims 1, 4-5, 7-27 and 52-57 are still pending and claims 2-3, 6, 28-51 have been cancelled.

2. In view of the appeal filed on 03/30/2009, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below. To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/XUAN M. THAI/

Supervisory Patent Examiner, Art Unit 3715

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 21-26 and 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 21 set forth the limitation of " .... *a filler material for selectively replacing the hypoechoic material included in the at least one opening"* that is considered to be indefinite since it is not clear if the applicant intends to include the filler material as part of the limitation in the claim. The examiner notes that one interpretation of the limitation " .... *a filler material for selectively replacing,"* is the medical simulator as claimed in claim 21 without the filler material being present in the medical simulator. It is not clear from the claim limitation if the applicant intend to include the filler material as part of the limitation of claim 21. Claims 22-26 are also rejected since they are dependant upon a rejected claim. Claim 21 is also rejected under 35 U.S.C 112, second paragraph, since the limitation "the hypoechoic material" in line 11, 14 and 16 of claim 21 lacks antecedent basis. For the purpose of the current examination, the examiner makes the assumption that applicant is referring to the limitation "solid or semi-solid hypoechoic material" limitation instead.

5. Similiarly, claim 58 set forth the limitation of " *a first material that can be selectively add to at least one of the plurality of opening by a us*er" that is considered to be indefinite since it is not clear if the applicant intends to include the first material as part of the limitation in the claim. The examiner notes that one interpretation of the limitation " ....*can be selectively added,"* is the medical simulator as claimed in claim 58 without the first material or a medical simulator with the first material placed outside of the simulator. As such, the examiner takes the position that it is not clear from the claim limitation what the applicant intends to be metes and bound for claim 58.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. **Claim 1, 4-5, 7-13, 15, 18-20, 22 and 27 rejected under 35 U.S.C. 103(a) as being unpatentable over Gain et al US 4,708,836, in view of NPL#1**

Claim 1: Gain provides a teaching for a medical simulator of a substantially life size model of human head and the model being at least fabricated from a first material (see Gain col. 5:43-67 artificial cranium), at least one simulated patent skull suture comprising a second material comprising at least of a solid (see Gain col. 11:45-57) and a scalp portions in which the patent skull suture is disposed such that the scalp portion of the model is covered with a layer of the second material the second material extending the beyond an opening in the first material defining the simulated patent skull sutures and covering the at least portion of the first material (see col. 14:15-25 "skin not only around cranium ...") . While Gain et al is silent on the limitation of "the echogenicity of the second material being substantially different than an echogenecity of said first material such that the each simulated skull sutures can be readily distinguished in an ultrasound image of said model." The difference in density of the first material –epoxy resin- and the second material –oil and silicon mixture- would have resulted in a difference in echogenecity such that the first and second material is readily distinguished in an ultrasound image of said model. The Gain reference provides a teaching of preventing tactile detection of a simulated patent skull sutures model, while enabling the simulated patent skull to be visually detected based upon an appearance of the simulated patent skull suture in an ultrasound image of said model (see col. 11:50-55 "skin")

Gain fails to provide a teaching of having an infant and simulated patent skull sutures. However, The infant skull model (see NPL #1), shows a photograph of a skull model that is substantially about the same size of an infant human head. The model disclosed shows visible anatomically correct patent sutures, such as: the metopic, sagital, coronal and lambdoid

sutures. The sutures portion of the model skull is shown as an opening on the model skull. Therefore, it would have been obvious to one of ordinary skilled in the art to include the feature of having a simulated patent skull sutures, as taught by NPL #1, because it would enable the Gain system to better approximate the physiology of an human infant.

With respect to the limitation of "to prevent the simulated patent skull suture from being identified tactilely" is currently treated as an intended use limitation and currently not given patentable weight.

Claim 4: While Gain does not provide an explicit teaching where the second material is hypoechoic. The examiner takes the position that **t**he difference in density of the first material –epoxy resin- and the second material –oil and silicon mixture-, would result in the second material being hypoechoic with respect to the first material.

Claim 5 and 22: While Gain does not provide an explicit teaching where the second material is hypoechoic. The examiner takes the position that **t**he difference in density of the first material –epoxy resin- and the second material –oil and silicon mixture-, would result in the second material being hypoechoic with respect to the first material. Therefore it would follow that the portion of the model that correspond to the first material would appear relatively bright and portions of the model corresponding to the second material appear relatively dark.

Claim 7-9: The examiner contends that the reference of Gain and NPL #1 fails to show an ultrasound simulator with a patent suture that is filled with a mixture of starch and glue (**claim 7**). Similarly, the reference does not show the glue in the mixture to be a casein-based glue (**claim 8**) or a synthetic resin-based glue (**claim 9**). Instead, the combination of the Gain and NPL#1 reference used a mixture of oil and silicon (see col. col. 11:45-57).

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to model the sutures using a mixture of oil and silicon.or starch and glue mixtures. Furthermore, one of ordinary skilled in the art would have expected

to both solutions to work equally well, the echogenicity of both materials are less than then solid portion of the skull. Therefore, it would have been prima facie obvious to modify Gain and NPL #1 to obtain the invention as specified in claim 7-9 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Gain and NPL#1.

Claim 10 and 11: Gain fails to provide a teaching of having a simulated patent skull sutures. The infant skull model (see NPL #1), shows a model substantially about the same size on human head. The model disclosed shows visible anatomically correct patent sutures, such as: the metopic, coronal, sagital and lambdoid sutures. Therefore, it would have been obvious to one of ordinary skilled in the art to include the feature of having a simulated patent skull sutures, as taught by NPL #1, because it would enable the Gain system to better approximate the physiology of an human infant.

However, the reference fails to show that the each of the sutures opening are beveled. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to model to use beveled opening or any other types of opening (e.g.: flush opening). Furthermore, one of ordinary skilled in the art would have expected to both solutions to work equally well, since the type of opening would not matter in its echogenicity properties with respect to an ultrasound device or training.

Therefore, it would have been prima facie obvious to modify NPL #1 to obtain the invention as specified in claim 10 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of NPL #1.

Claim 12: Gain provides a teaching where the medical simulator comprised of at least one simulated fused skull sutures (see Gain FIG. 2).

Claim 13: Gain provides a teaching where the medical simulator comprised of at least one simulated fused skull sutures made from a first material (see Gain col. 5:43-67 artificial cranium).

Claim 18 and 19: Gain provides a teaching of an opaque layer configured to cover each of the simulated skull sutures and the scalp areas (see col. 12:44-56). The limitation of "so that a trainee cannot readily visually determine whether a specific skull sutures is patent or skull by inspecting the model" is being treated as an intended use limitation and currently not given patentable weight.

Claim 20: Gain provides in teaching where the head is utilized for the substantially life size model of a human head (see col. 2:7-14).

Claim 27: Gain provides a teaching for a medical simulator of a substantially life size model of human head and the model being at least fabricated from a first material (see Gain col. 5:43-67 artificial cranium) and a second material comprising at least of a solid (see Gain col. 11:45-57). While Gain et al is silent on the limitation of "the echogenicity of the second material being substantially different than an echogenecity of said first material such that the each simulated skull sutures can be readily distinguished in an ultrasound image of said model." The difference in density of the first material –epoxy resin- and the second material –oil and silicon mixture- would have resulted in a difference in echogenecity such that the first and second material be readily distinguished in an ultrasound image of said model.

Gain fails to provide a teaching of having an infant head model and a simulated patent skull sutures. However, The infant skull model (see NPL #1), shows a photograph of a skull model that is substantially about the same size of an infant human head. The model disclosed shows visible anatomically correct patent sutures, such as: the metopic, sagital, coronal and lambdoid sutures. The sutures portion of the model skull is shown as an opening on the model skull. Therefore, it would have been obvious to one of ordinary skilled in the art to include the feature of having a simulated patent skull sutures, as taught by NPL #1, because it

would enable the Gain system to better approximate the physiology of an human infant. While Gain does not provide an explicit teaching where the second material is hypoechoic. The examiner takes the position that **t**he difference in density of the first material –epoxy resin- and the second material –oil and silicon mixture-, would result in the second material being hypoechoic with respect to the first material. Therefore it would follow that the portion of the model that correspond to the first material would appear relatively bright and portions of the model corresponding to the second material appear relatively dark

8. **Claim 14, 16-17, 21-26 and 52-58 rejected under 35 U.S.C. 103(a) as being unpatentable over Gain et al US 4,708,836, in view of NPL#1, in view of Bergman US 5,609,485**

Claim 14 and 25: The Gain reference fails to provide a teaching of each simulated fused skull suture comprised of an opening within said first material, each opening corresponding to a simulated skull structure being filled with a third material, the echogenicity of the third material being substantially distinguishable from the second material, so that each opening correspond to a simulated skull sutures can be readily distinguishable from an opening corresponding to a simulated patent skull sutures in an ultrasound image of a said model.

However, the Bergman reference provides a teaching of an opening within said first material, each opening corresponding to a simulated skull structure being filled with a third material, the echogenicity of the third material being substantially distinguishable from the second material, so that each opening correspond to a simulated skull sutures can be readily distinguishable from an opening corresponding to a simulated patent skull sutures in an ultrasound image of a said model (see Bergman 8:35-50). Therefore, it would have been obvious to one of ordinary skilled in the art at the time of invention of an opening within said first material, each opening corresponding to a simulated skull structure being filled with a third material, the echogenicity of the third material being substantially distinguishable from

the second material, so that each opening correspond to a simulated skull sutures can be readily distinguishable from an opening corresponding to a simulated patent skull sutures in an ultrasound image of a said model, as taught by Bergman, in order to provide any training in the dynamic use of ultrasound on a simulated patient, having any one of a number of desired training pathologies (see col. 2:1-5).

Claim 15: The Gain reference fails to provide a teaching wherein the echogenicity of the third material is substantially similar to the first material, such that in an ultrasound image of the model, portions of the model comprising the first material are not readily distinguishable from portions of the model comprising the third material. However, the Gain reference provides a teaching of having a patent suture filled with the first material (see FIG 2 between item 2 and 6). However, the same result can also be achieved by using the first material for the third material. Since they are made from the same material, the material should have similar echogenic properties.

Claim 16-17 and 56: The Gain reference fail to provide the third material comprises a synthetic elastomer and the elastomer comprises of dimethyl siloxane, hydroxyl-terminated polymers and silica.

Instead the Gain reference provides a teaching of using epoxy resin instead of a synthetic elastomer and the elastomer comprises of dimethyl siloxane, hydroxyl-terminated polymers and silica as claimed.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use epoxy-resin, because Applicant has not disclosed that a synthetic elastomer and the elastomer comprises of dimethyl siloxane, hydroxyl-terminated polymers, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the epoxy resin and a synthetic elastomer, to perform equally well for the purpose of having the same echogenic properties as the first material.

Therefore, it would have been prima facie obvious to modify Gain to obtain the invention as specified in claim 16-17 and 56 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Gain.

Claim 21: Gain provides a teaching for a medical simulator of a substantially life size model of human head said model having opening and the model being at least fabricated from a first material (see Gain col. 5:43-67 artificial cranium) and a solid being included in each opening that opening correspond to a simulated suture d (see Gain col. 11:45-57). While Gain et al is silent on the limitation of "the echogenicity of the second material being substantially different than an echogenecity of said first material such that the each simulated skull sutures can be readily distinguished in an ultrasound image of said model." The difference in density of the first material –epoxy resin- and the second material –oil and silicon mixture- would have resulted in a difference in echogenecity such that the first and second material is readily distinguished in an ultrasound image of said model. The Gain reference provides a teaching of preventing tactile detection of a simulated patent skull sutures model, while enabling the simulated patent skull to be visually detected based upon an appearance of the simulated patent skull suture in an ultrasound image of said model (see col. 11:50-55 "skin")

Gain fails to provide a teaching of an infant size, and having a simulated patent skull sutures. However, The infant skull model (see NPL #1), shows a photograph of a skull model that is substantially about the same size of an infant human head. The model disclosed shows visible anatomically correct opening to model the patent sutures, such as: the metopic, sagital, coronal and lambdoid sutures. The sutures portion of the model skull is shown as an opening on the model skull. Therefore, it would have been obvious to one of ordinary skilled in the art to include the feature of having a simulated patent skull sutures, as taught by NPL #1, because it would enable the Gain system to better approximate the physiology of an human infant.

The Gain fails to provide a teaching of a filler material for selectively replacing the hypoechoic material in at least one selected opening, the filler material having an echogenicity

that is generally similar to that of the portions of the model not corresponding to the simulated skull suture, so that each opening in which the filler material replaces the hypoechoic material simulates a fused skull suture in an ultrasonic image, the model being modified able between training sessions by replacing the hypoechoic material the filler material from the at least one opening and adding the filler material within at least one other different opening. However, the Bergman provides a teaching of selectively replacing the hypoechoic material in at least one selected opening, the filler material having an echogenicity that is generally similar to that of the portions of the model not corresponding to the simulated skull suture, so that each opening in which the filler material replaces the hypoechoic material simulates a fused skull suture in an ultrasonic image, the model being modified able between training sessions by replacing the hypoechoic material the filler material from the at least one opening and adding the filler material within at least one other different opening (see col. 8:35-50). Therefore, it would have been obvious to one of ordinary skilled in the art to include the feature of selectively modifying the model between training sessions by enabling a filler material to be added within at least one selected opening, the filler material having an echogenicity that is generally similar to that of the portions of the model not corresponding to the simulated skull suture, so that each opening in which the filler material is added simulates a fused skull suture in an ultrasonic image, the model being modified between training sessions by removing the filler material from the at least one opening and adding the filler material within at least one other different opening, as taught by Bergman, in order to provide any training in the dynamic use of ultrasound on a simulated patient, having any one of a number of desired training pathologies (see col. 2:1-5).

Claim 22: While Gain does not provide an explicit teaching where the second material is hypoechoic. The examiner takes the position that **t**he difference in density of the first material –epoxy resin- and the second material –oil and silicon mixture-, would result in the second material being hypoechoic with respect to the first material. Therefore it would follow that the

portion of the model that correspond to the first material would appear relatively bright and portions of the model corresponding to the second material appear relatively dark.

C**laim 23 and 24:** While Gain does not provide an explicit teaching where the second material is hypoechoic. The examiner takes the position that **t**he difference in density of the first material –epoxy resin- and the second material –oil and silicon mixture-, would result in the second material being hypoechoic with respect to the first material.

The Cecchi reference provides a teaching of modifying of lowering or increasing the density of the material to control the echogenicity properties of the material. Therefore, it would have been obvious to one of ordinary skilled in the art to manipulate the density of the second material, as taught by Cecchi, because it would enable the head model to have the correct echogenic properties.

Claim 25: The Gain reference fails to provide a teaching of each simulated fused skull suture comprised of an opening within said first material, each opening corresponding to a simulated skull structure being filled with a third material, the echogenicity of the third material being substantially distinguishable from the second material, so that each opening correspond to a simulated skull sutures can be readily distinguishable from an opening corresponding to a simulated patent skull sutures in an ultrasound image of a said model.

However, the Bergman reference provides a teaching of an opening within said first material, each opening corresponding to a simulated skull structure being filled with a third material, the echogenicity of the third material being substantially distinguishable from the second material, so that each opening correspond to a simulated skull sutures can be readily distinguishable from an opening corresponding to a simulated patent skull sutures in an ultrasound image of a said model (see Bergman 8:35-50). Therefore, it would have been obvious to one of ordinary skilled in the art at the time of invention of an opening within said first material, each opening corresponding to a simulated skull structure being filled with a third material, the echogenicity of the third material being substantially distinguishable from

the second material, so that each opening correspond to a simulated skull sutures can be readily distinguishable from an opening corresponding to a simulated patent skull sutures in an ultrasound image of a said model, as taught by Bergman, in order to provide any training in the dynamic use of ultrasound on a simulated patient, having any one of a number of desired training pathologies (see col. 2:1-5).

Claim 26: Gain fails to provide a teaching of having a simulated patent skull sutures. However, the infant skull model (see NPL #1), shows a model substantially about the same size on human head. The model disclosed shows visible anatomically correct patent sutures, such as: the metopic, coronal, sagital and lambdoid sutures. The reference also shows that the sagital and metopic sutures are formed in a way that the opposites walls of the opening would meet in an end-to-end fashion. Therefore, it would have been obvious to one of ordinary skilled in the art to include the feature of having a simulated patent skull sutures, as taught by NPL #1, because it would enable the Gain system to better approximate the physiology of an human infant.

However, the reference fails to show that the each of the sutures opening are beveled. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to model to use beveled opening or any other types of opening (e.g.: flush opening). Furthermore, one of ordinary skilled in the art would have expected to both solutions to work equally well, since the type of opening would not matter in its echogenicity properties with respect to an ultrasounic device or training.

Therefore, it would have been prima facie obvious to modify NPL #1 to obtain the invention as specified in claim 26 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of NPL #1.

Claim 52: Gain provides a teaching of medical simulator of substantially life-size model of human head (see col. 2:7-14) including two eyes, mouth, ears (see col. 11:17-30). While Gain

et al is silent on the limitation of "the echogenicity of the second material being substantially different than an echogenecity of said first material such that the each simulated skull sutures can be readily distinguished in an ultrasound image of said model." The difference in density of the first material –epoxy resin- and the second material –oil and silicon mixture- would have resulted in a difference in echogenecity such that the first and second material be readily distinguished in an ultrasound image of said model.

Gain fails to provide a teaching of having an infant and simulated patent skull sutures. However, The infant skull model (see NPL #1), shows a photograph of a skull model that is substantially about the same size of an infant human head. The model disclosed shows visible anatomically correct patent sutures, such as: the metopic, sagital, coronal and lambdoid sutures. The sutures portion of the model skull is shown as an opening on the model skull. Therefore, it would have been obvious to one of ordinary skilled in the art to include the feature of having a simulated patent skull sutures, as taught by NPL #1, because it would enable the Gain system to better approximate the physiology of an human infant.

The Gain reference do not provide a teaching of skull suture that can be selectively modified to appear as a simulated skull suture and non suture portiosns fo the the model and from eachh simulated fused suture. However, the Bergman reference provides a teaching of a skull suture that can be selectively modified to appear as a simulated skull suture and non suture portiosns fo the the model and from eachh simulated fused suture (see col. 8:35-50). Therefore, it would have been obvious to one ordinary skilled in the art to include the feature of of skull suture that can be selectively modified to appear as a simulated skull suture and non suture portiosns fo the the model and from eachh simulated fused suture, as taught Bergman, in order to provide any training in the dynamic use of ultrasound on a simulated patient, having any one of a number of desired training pathologies (see col. 2:1-5).

Claim 53: Gain provides a teaching of medical simulator of substantially life-size model of human head (see col. 2:7-14) including two eyes, mouth, ears (see col. 11:17-30). While Gain

et al is silent on the limitation of "the echogenicity of the second material being substantially different than an echogenecity of said first material such that the each simulated skull sutures can be readily distinguished in an ultrasound image of said model." The examiner takes the position that the difference in density of the first material –epoxy resin- and the second material –oil and silicon mixture-, would result in the second material being hypoechoic with respect to the first material. Therefore it would follow that the portion of the model that correspond to the first material would appear relatively bright and portions of the model corresponding to the second material appear relatively dark.

Gain fails to provide a teaching of having a simulated patent skull sutures. However, The infant skull model (see NPL #1), shows a photograph of a skull model that is substantially about the same size of an infant human head. The model disclosed shows visible anatomically correct patent sutures, such as: the metopic, sagital, coronal and lambdoid sutures. The sutures portion of the model skull is shown as an opening on the model skull. Therefore, it would have been obvious to one of ordinary skilled in the art to include the feature of having a simulated patent skull sutures, as taught by NPL #1, because it would enable the Gain system to better approximate the physiology of an human infant.

The Gain fails to provide a teaching of means for selectively modifying the model between training sessions by enabling a filler material to be added within at least one selected opening, the filler material having an echogenicity that is generally similar to that of the portions of the model not corresponding to the simulated skull suture, so that each opening in which the filler material is added simulates a fused skull suture in an ultrasonic image, the model being modified between training sessions by removing the filler material from the at least one opening and adding the filler material within at least one other different opening. However, the Bergman provides a teahcing of selectively modifying the model between training sessions by enabling a filler material to be added within at least one selected opening, the filler material having an echogenicity that is generally similar to that of the portions of the model not

corresponding to the simulated skull suture, so that each opening in which the filler material is added simulates a fused skull suture in an ultrasonic image, the model being modified between training sessions by removing the filler material from the at least one opening and adding the filler material within at least one other different opening (see col. 8:35-50). Therefore, it would have been obvious to one of ordinary skilled in the art to include the feature of selectively modifying the model between training sessions by enabling a filler material to be added within at least one selected opening, the filler material having an echogenicity that is generally similar to that of the portions of the model not corresponding to the simulated skull suture, so that each opening in which the filler material is added simulates a fused skull suture in an ultrasonic image, the model being modified between training sessions by removing the filler material from the at least one opening and adding the filler material within at least one other different opening, as taught by Bergman, in order to provide any training in the dynamic use of ultrasound on a simulated patient, having any one of a number of desired training pathologies (see col. 2:1-5).

Claims 54 and 57: Gain provides a teaching for a medical simulator of a substantially life size model of human head and the model being at least fabricated from a first material (see Gain col. 5:43-67 artificial cranium) and a second material comprising at least of a solid (see Gain col. 11:45-57). While Gain et al is silent on the limitation of "the echogenicity of the second material being substantially different than an echogenecity of said first material such that the each simulated skull sutures can be readily distinguished in an ultrasound image of said model." The difference in density of the first material –epoxy resin- and the second material – oil and silicon mixture- would have resulted in a difference in echogenecity such that the first and second material be readily distinguished in an ultrasound image of said model.
Gain fails to provide a teaching of having a simulated patent skull sutures. However, The infant skull model (see NPL #1), shows a photograph of a skull model that is substantially about the same size of an infant human head. The model disclosed shows visible anatomically

correct patent sutures, such as: the metopic, sagital, coronal and lambdoid sutures. The sutures portion of the model skull is shown as an opening on the model skull. Therefore, it would have been obvious to one of ordinary skilled in the art to include the feature of having a simulated patent skull sutures, as taught by NPL #1, because it would enable the Gain system to better approximate the physiology of an human infant.

The Gain reference fails to provide a teaching of each simulated fused skull suture comprised of an opening form in said first material, each opening corresponding to a simulated skull structure being filled with a third material, the echogenicity of the third material being substantially distinguishable from the second material, so that each opening correspond to a simulated skull sutures can be readily distinguishable from an opening corresponding to a simulated patent skull sutures in an ultrasound image of a said model.

The Gain reference provides a teaching of a third material being disposed within each opening corresponds to simulated skull suture, an echogenecity of the third material being substantially different then the echogenicity of the second material so that each opening corresponding to a simulated skull suture can be readily distinguish from an opening to a simulated skull suture in an ultrasound image of said model. However, the Bergman reference provides a third material being disposed within each opening corresponds to simulated skull suture, an echogenecity of the third material being substantially different then the echogenicity of the second material so that each opening corresponding to a simulated skull suture can be readily distinguish from an opening to a simulated skull suture in an ultrasound image of said model (see (see col. 8:35-50). Therefore, it would have been obvious to one of ordinary skilled in the art to include the feature of selectively modifying the model between training sessions by enabling a filler material to be added within at least one selected opening, the filler material having an echogenicity that is generally similar to that of the portions of the model not corresponding to the simulated skull suture, so that each opening in which the filler material is added simulates a fused skull suture in an ultrasonic image, the model being modified between

training sessions by removing the filler material from the at least one opening and adding the filler material within at least one other different opening, as taught by Bergman, in order to provide any training in the dynamic use of ultrasound on a simulated patient, having any one of a number of desired training pathologies (see col. 2:1-5).

Claims 58: The Gain provides a teaching for a medical simulator of a substantially life size model of human head and the model being at least fabricated from a first material (see Gain col. 5:43-67 artificial cranium) and a second material comprising at least of a solid (see Gain col. 11:45-57). While Gain et al is silent on the limitation of "the echogenicity of the second material being substantially different than an echogenecity of said first material such that the each simulated skull sutures can be readily distinguished in an ultrasound image of said model." The difference in density of the first material –epoxy resin- and the second material – oil and silicon mixture- would have resulted in a difference in echogenecity such that the first and second material readily distinguished in an ultrasound image of said model. The Gain reference provides a teaching of a first filler material having an echogenecity of the about equal that of the portion of the model not corresponding to simulated patent skull suture (see FIG 2 between item 2 and 6). The same result can also be achieved by using the first material for the third material. Since they are made from the same material, the material should have similar echogenic properties.

Gain fails to provide a teaching of having a simulated patent skull sutures. However, The infant skull model (see NPL #1), shows a photograph of a skull model that is substantially about the same size of an infant human head. The model disclosed shows visible anatomically correct patent sutures, such as: the metopic, sagital, coronal and lambdoid sutures. The sutures portion of the model skull is shown as an opening on the model skull. Therefore, it would have been obvious to one of ordinary skilled in the art to include the feature of having a simulated patent skull sutures, as taught by NPL #1, because it would enable the Gain system to better approximate the physiology of an human infant.

The examiner notes that the limitation of "... that can be selectively added to at least one of plurality opening by a user " and "... such that when the first filler material is added to at least one opening to at least one opening the first filler material in opening creates a simulated fused skull suture" are interpreted as intended use limitation that may or may not be present in the model.

Claim 55: The Gain reference fails to provide a teaching wherein the echogenicity of the third material is substantially similar to the first material, such that in an ultrasound image of the model, portions of the model comprising the first material are not readily distinguishable from portions of the model comprising the third material.

However, the Gain reference provides a teaching of having a patent suture filled with the first material (see FIG 2 between item 2 and 6). However, the same result can also be achieved by using the first material for the third material. Since they are made from the same material, the material should have similar echogenic properties.

Response to Arguments

9. With respect to the after final argument submitted on 01/28/2009, the examiner would like to note that upon further consideration the after final amendment submitted on 01/28/2009 did raise a new issue that would further consideration. Specifically, the amendment submitted on 01/28/2009 necessitated the new ground of rejection applied on claim 1, 4-5, 7-27 and 52-57 and new rejection under 35 U.S.C 112, second paragraph, on claim 21 and 58. Therefore, the prosecution of the case has been re-opened in order to address the new rejection.

10. The applicant argues that the Gain teaching do not provide a teaching of a patent sutures and not provide a teaching of a having fine anatomical detail and the combination between Gain reference specifically excludes the addition of suture in the cranium model. The examiner would like to point out that that the cranium the Gain teaching uses a real cranium

and uses the impression of a real human cranium to the obtain the artificial cranium (see col. 2:30-40) and notes that the external shape of the artificial cranium have to be identical to that of the fresh cranium (see col. 2:15-17). The word identical in this particular case can be defined as "having such close resemblance as to be essentially the same" (see Merriam-Webster Dictionary). The examiner notes that fused skull sutures are anatomical features that present in every adult human skull cranium (see grays anatomy page 6 line 11-16 and page 3 line 6-9). Human cranium refers to the part of the skull that protects the brain that consists of 8 bones: occipital, two parietals, frontal, two temporal, sphenoidal and ethomiodal (see grays anatomy page 1 "Cranium"). These fused skull suture are anatomical feature that can be found in between these 8 bone that makes up the human cranium. It would have been necessary in the Gain teaching to show these 8 distinct and different bone structures and the connection between these 8 bones. A failure to show these detail would result in an external shape of the artificial cranium that is not identical to the fresh cranium. The examiner would like to point out that the Gain reference teaches in its best embodiment that the external shape of the cranium is identical to that of the fresh cranium. As such, the examiner takes the position that these features would have been an inherent feature of the Gain reference.

11. With respect to applicant's argument to the Cecchi reference is no longer part of the rejection. The limitation that necessitates the use of the Cecchi reference is no longer present in the claim.

12. With respect to the combination of Gain et al NPL#1 and Bergman; the applicant argues that the Bergman fails to provide a teaching of selectively modifying a model between traning session by enabling a filler material to be added to the opening. The examiner respectfully disagrees. The Bergman reference provide a teaching of embedding a transmitter that in the simulated body (see col. 8:30-35); furthermore the Bergman reference also teaches that the transmitter can be embedded in different part of the body. As such, the examiner takes the position that the such combination is sufficient to overcome the limitation "...

selectively enabling a filler material to be added to the opening." With regard to the limitation of "being modified in between training session." The examiner currently interprets this limitation as an intended use limitation. The examiner notes that the Bergman reference suggests that the transmitter location can be modified to suit different training requirement. The difference between the combination of the prior arts and the applicant claimed invention seems to rely on the timing when a certain modification takes place. The examiner also notes that since the Bergman reference suggest modifying transmitter location to suit different training requirement it would also be capable to be modified in between training session. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT J. UTAMA whose telephone number is (571)272-1676. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Xuan Thai can be reached on (571)272-7147. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. J. U./
Examiner, Art Unit 3715

/XUAN M. THAI/
Supervisory Patent Examiner, Art Unit 3715